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Proposed Maximum Residue Limit PMRL2015-20

Tembotrione

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that registration of the new end-use product Laudis Herbicide, containing the registered technical grade active ingredient tembotrione and the safener isoxadifen-ethyl is acceptable. The specific uses approved in Canada are detailed on the label of Laudis Herbicide, *Pest Control Products Act* Registration Number 31721.

The evaluation of this tembotrione application indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally specified as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product is made from it.

Consultation on the proposed MRL for tembotrione is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRL can be found in Appendix I. The currently established MRLs of 0.08 ppm in/on field corn and 0.04 ppm in/on sweet corn kernels plus cob with husks removed for isoxadifen-ethyl are sufficient to cover residues resulting from these new uses and are therefore unaffected by this MRL action.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to replace the MRL already established for tembotrione, is as follows.

Table 1 Proposed Maximum Residue Limits for Tembotrione

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Tembotrione	2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione	0.01[2]	Sweet corn kernels plus cob with husks removed

[1] ppm = parts per million

[2] The current tembotrione residue definition for all commodities is captured as "2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione, including the metabolite 2-[2-chloro-4-(methylsulfonyl)-3-[2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione". The MRL of 0.01 ppm for residues of tembotrione only is proposed to replace the established MRL of 0.04 ppm for the combined residues of tembotrione and the metabolite 2-[2-chloro-4-(methylsulfonyl)-3-[2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione for sweet corn kernels plus cob with husks removed. The MRL of 0.04 ppm for imported sweet corn was based on residue data from sweet corn field trials conducted at a total exaggerated rate of 182-190 g a.i./ha.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRL proposed for tembotrione in Canada is the same as the corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there is no Codex MRL[1] listed for tembotrione in or on any commodity on the Codex Alimentarius Pesticide Residues in Food webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for tembotrione up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for tembotrione in sweet corn were submitted to support the domestic use of the new end-use product Laudis Herbicide containing the registered technical grade active ingredient tembotrione.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for tembotrione was based upon the submitted sweet corn field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for sweet corn. The currently established MRL of 0.02 ppm in/on field corn for tembotrione is sufficient to cover residues.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate (g a.i./ha)[1]	Preharvest Interval (days)	Maximum Residues[2] (ppm)	Minimum Residues[2] (ppm)	Experimental Processing Factor
Sweet corn kernels plus cob with husks removed	Single Foliar broadcast application/ 89-96	36-70	< 0.01	< 0.01	Not applicable

1 g a.i./ha = grams of active ingredient per hectare.
2 Tembotrione only.

No increase to the dietary burden of livestock is expected when field and sweet corn are treated according to the approved label of Laudis Herbicide.

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of tembotrione. Residues of tembotrione in field corn and sweet corn at the proposed and established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.